METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

TECHNICAL DATA SHEET

151372-TDS-ENG-2024

PROCAINAMIDA HCL (EUR. PH.)		
DESCRIPTION DCI: PROCAINAMIDE HYDROCHLORIDE	DESCRIPTION DOE: PROCAINAMIDA HIDROCLORURO	
CAS Nº: 614-39-1	EC Nº: 210-381-7	AEMPS CODE: 2207CH
MOL. WEIGHT: 271.79	MOL. FORMULA: C13H22ClN3O	ARTICLE CODE: 151372

ATTRIBUTES	SHOULD BE
Appearance	White or very slightly yellow, crystalline powder; hygroscopic
Solubility	Very soluble in water, freely soluble in alcohol, slightly soluble in acetone
Identification C	Complies
Identification D	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. B6
pH	5.6 - 6.3
Related substances	=< 0.5 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the container tightly closed in a cool, dry and well-ventilated place.

REMARKS

Procainamide Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Properties
PROCAINAMIDE is a medication that acts at the heart level as a class I antiarrhythmic agent, indicated in the treatment of certain heart rhythm disorders. It is administered intravenously or orally and acts by blocking the sodium channels in the heart muscle, thus prolonging the duration of the action potential of the cardiac cell.

Adverse effects
PROCAINAMIDE has extracardiac effects, producing a reduction in peripheral vascular resistance that can cause arterial hypotension, especially with the accelerated infusion of the drug intravenously.
The most notable adverse reactions include the appearance of a syndrome similar to systemic lupus erythematosus, characterized by rash, fever, muscle aches and arthritis. In some patients, non-infectious pleuritis or pericarditis may appear. All these reactions are more frequent with prolonged use of the medication. Occasionally, diarrhea, hepatitis and agranulocytosis have been reported.